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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/198,798 11/24/98 LICHTEN

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EXAMINER

HM12/0815

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ART UNIT

PAPER NUMBER

1618

DATE MAILED:

*Amendment out 08/15/00  
due 11-15-00  
\* MAX \* 2-15-01*

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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AUG 21 2000  
GIFFORD, KRASS, GROH, SPRINKLE,  
ANDERSON & CITKOWSKI, P.C.

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# Office Action Summary

Application No.

09/198,798

Applicant(s)

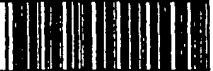
Lichten

Examiner

Barbara Badio

Group Art Unit

1616



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-50 is/are pending in the application.

Of the above, claim(s) 15-29 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-14 and 30-50 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —



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### **First Office Action on the Merits**

#### ***Election/Restriction***

1. Claims 15-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6, 8-13, 30-35, 34-42, 44 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for testosterone or pharmaceutically acceptable salts, esters, amides and derivatives thereof as defined on page 15 of the present specification, does not reasonably provide enablement for analogs, all derivatives and prodrugs thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The instant claims are drawn to the use of testosterone, or the analogs, derivatives and pharmaceutically acceptable salts, esters, amides and prodrugs thereof in controlling serum-glucose levels. The present specification discloses some examples of derivatives testosterone (see page 15 of the specification). The specification lacks description and a process of making analogs, other derivatives and prodrugs of testosterone and, thus, does not provide a method of using said compounds as claimed by the instant claims. It does not enable the ordinary artisan in the art guidance as to how to make and use the invention commensurate in scope with these claims.

In regards to the term "derivatives", it is suggested that applicant either remove said from the claims or rewrite the claim to read "derivatives selected from the group consisting of ....." incorporating the examples set forth on page 15 of the present specification.

4. Claims 1-6, 8-13, 30-35, 37-42, 44 and 46-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The instant claims recite the terms "analogs and derivatives". The specification provides examples of the term "derivatives" and not "analogs". If applicant intends "derivatives" and "analogs" to refer to different compounds, the specification lacks description of the term "analogs" and, thus, does not convey to the ordinary artisan in the art that applicant had possession of the claimed invention. If applicant intends derivatives and analogs to refer to the same compounds, it is suggested that the term "analogs" be removed from the claims.

5. Claims 1-14 and 30-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method for controlling serum-glucose levels in a subject by administering a serum-glucose lowering amount of testosterone.... to said subject. The specification describes the administration of said compounds to a subject having high serum-glucose levels in order lower said levels. The claimed method includes administration to any subject. The specification does not provide enablement for the administration of the claimed compounds to any subject and, thus, does not enabled the skilled artisan to use the invention.

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6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-7, 8-14 and 30-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6, 8-13, 30-35, 37-42, 44 and 46-50 recite "testosterone or the analogs, derivatives, and pharmaceutically acceptable salts, esters, amides, and prodrugs thereof". The specification sets forth some examples of derivatives, salts, esters and amides contemplated. However, apart from the examples recited by the present specification, the ordinary artisan would be unable to determine the metes and bound of the present invention. For example, it is not clear what is encompassed by the term "prodrugs". The specification defines "prodrugs" as compounds that are rapidly transformed in vivo to yield the compound of the above formulae. It is not clear what formulae applicant is referring to or what is encompassed by "compounds that are rapidly transformed in vivo to yield the compound of the above formulae". It is also not clear what other compounds are encompassed by the term "derivatives" apart from those disclosed by the present specification or what is encompassed by the term "analog" which is not defined by the specification.

Claims 7, 14, 36, 43 and 45 recite "wherein said testosterone derivative comprises dihydrotestosterone". It is not clear what is meant by "said testosterone

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derivative **comprises** dihydrotestosterone". Is applicant claiming "said testosterone derivative **is** dihydrotestosterone" or wherein said testosterone derivative **is selected from** dihydrotestosterone and other derivatives? If applicant is claiming the latter, what other derivatives are intended. For the purpose of art rejection, the examiner assumes applicant intends any derivatives of testosterone.

In addition, claims 44-50 recite "[a] method for identifying and treating insulin resistance....". A claim should recite a single invention. The language of the instant claims suggest two invention, a method of identifying which involves an assay and a method of treatment. For the purpose of art rejection and based on applicant's election of the method of use of the claimed compounds, claims 44-50 will be read as "a method of treating insulin resistance....".

8. Claim 2 recites the limitation "said intramuscularly" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The instant claim is dependent on claim 1 which does not recite a method of administration.

Claims 3-5, 9-12, 31-34, 38-41 and 46-49 recite either "said intramuscularly" or "said subcutaneously" and, therefore, are rejected for the reason given above.

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9. Regarding claims 2, 4, 5, 9, 11, 12, 31, 33, 34, 38, 40, 41, 46, 48 and 49, the term "includes" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 8, 9, 30, 31, 37, 38, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Coleman et al.

Coleman et al. teach DHEA (dehydroepiandrosterone) is a potent antihyperglycemic and antidiabetic agent (see page 30, col. 2, Discussion). The method of use taught by the reference is encompassed by the instant claims.

12. Claims 1, 2, 8, 9, 30, 31, 37, 38, 44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Moller et al. and Mauriello et al.

Moller et al. and Mauriello et al. teach the drop in the need for oral hypoglycemics and/or insulin in diabetic patients using testosterone or testosterone



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propionate (see Moller et al., page 20, lines 3-17; Mauriello et al., page 136, 5th paragraph; see also page 12, lines 16-22 of the present specification). The references in essence teach the hypoglycemic effect of testosterone and testosterone propionate. Therefore, the method of use taught by the reference is encompassed by the instant claims.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 1-14 and 30-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coleman et al., Moller et al. or Mauriello et al.

Coleman et al. teach DHEA (dehydroepiandrosterone) is a potent antihyperglycemic and antidiabetic agent (see page 30, col. 2, Discussion).

Moller et al. and Mauriello et al. teach the drop in the need for oral hypoglycemics and/or insulin in diabetic patients using testosterone or testosterone propionate (see Moller et al., page 20, lines 3-17; Mauriello et al., page 136, 5th

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paragraph; see also page 12, lines 16-22 of the present specification). The references in essence teach the hypoglycemic effect of testosterone and testosterone propionate.

The instant claims differ from the references cited above by reciting a broader genus than the prior art. However, Moller et al. teach the use of anabolic steroids in the reduction of blood sugar, lowering the insulin requirements and restoring activity in insulin-resistant patients. Testosterone and derivatives of testosterone are known in the art to be anabolic steroids and, thus, the ordinary artisan in the art would have the reasonable expectation that any testosterone derivative, including those of the instant invention, would be useful in lowering serum-glucose levels and, thus, useful in the treatment of diseases resulting from hyperglycemia. The ordinary artisan would have been motivated to use other testosterone derivatives in order to find the most efficacious compound(s) in lowering blood glucose level.

Claims 3-5, 10-12, 32-34, 39-41 and 47-49 differ from the prior art by reciting different modes of administration of the claimed compound(s). However, the preparation of various pharmaceutical formulation is well known in the art and, thus, is within the level of skill of the ordinary artisan.

Claims 6, 13, 35, 42 and 50 differ from the prior art by reciting specific dosages. The determination of the amount of testosterone or its derivatives needed to reduce serum-glucose level involves routine experimentation and within the level of skill of the ordinary artisan in the art.

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***Telephone Inquiry Contacts***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*Barbara Badio*

Barbara Badio  
Primary Examiner  
Art Unit 1616

August 11, 2000